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Filing Date	Jan 11, 2002
First Named Inventor	Yu, Xuanchuan
Art Unit	1652
Examiner Name	S. Swope
Attorney Docket Number	LEX-0298-USA

ENCLOSURES *(check all that apply)*

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- [ ] Appeal Communication to Board of Appeals and Interferences
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Lexicon Genetics Incorporated Lance K. Ishimoto Reg. No. 41,866
Signature	Lance K. Ishimoto by David W. Hobbie David W. Hobbie Reg. No. 41,071
Date	March 22, 2004

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Filed In Triplicate

Reply Brief

Applicant(s)	Hu and Turner
Application #	10/044,807
Date Filed	January 11, 2002
Title	Human Protease Polynucleotides and Compositions Comprising the Same (As Amended)
Attorney Docket #	LEX-0298-USA
Group Art Unit	1652
Examiner	S. Swope

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Yu and Turner, Jr.		
Serial No.:	10/044,807	Group Art Unit:	1652
Filed:	1/11/2002	Examiner:	S. Swope
For:	Human Protease Polynucleotides and Compositions Comprising the Same (As Amended)	Attorney Docket No.:	LEX-0298-USA

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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REPLY BRIEF

Sir:

Appellants hereby submit an original and two copies of this Reply Brief to the Board of Patent Appeals and Interferences ("the Board") in response to the Examiner's Answer mailed on January 21, 2004. The Reply Brief is due on March 21, 2004, which falls on a Sunday and is therefore extended until Monday, March 22, 2004 under 37 C.F.R. § 1.7. This Reply Brief is therefore timely submitted, and Appellants believe no fees are due in connection with this Reply Brief. However, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason related to this communication, the Commissioner is authorized to charge any underpayment or credit any overpayment to Lexicon Genetics Incorporated Deposit Account No. 50-0892.

I. REAL PARTY IN INTEREST

Appellants agree with the Examiner's assertion that "(a) statement identifying the real party in interest is contained in the brief" (Examiner's Answer at page 2).

II. RELATED APPEALS AND INTERFERENCES

Appellants agree with the Examiner's assertion that "Appellant's (*sic*) brief includes a statement that there are no related appeals or interferences" (Examiner's Answer at page 2).

III. STATUS OF THE CLAIMS

Appellants agree with the Examiner's assertion that "(t)he statement of the status of the claims contained in the brief is correct" (Examiner's Answer at page 2).

IV. STATUS OF THE AMENDMENTS

Appellants agree with the Examiner's assertion that "(t)he statement of the status of the amendments contained in the brief is correct" (Examiner's Answer at page 2).

V. SUMMARY OF THE INVENTION

Appellants disagree with the Examiner's assertion that "(t)he summary of invention contained in the brief is substantially correct" (Examiner's Answer at page 2), and point out that the Examiner's allegation that the summary "includes discussion of Applicant's (*sic*) deductions for the utility of the polypeptide encoded by the polynucleotide of SEQ ID NO: 1" (Examiner's Answer at page 2) is erroneous. Appellants submit that the summary of **the invention** includes aspects of **the invention** that are described in the specification as originally filed, and are thus properly included in this section of the Appeal Brief. That the Examiner disagrees with Appellants' assertions concerning the **utility** of the present invention is blatantly obvious, given the fact that an Appeal Brief needed to be filed in the first place, but this does not mean that the summary of **the invention** as set forth by Appellants in the Appeal Brief is only "substantially correct".

VI. ISSUES ON APPEAL

Appellants agree with the Examiner's assertion that "(t)he appellant's (*sic*) statement of the issues in the brief is correct" (Examiner's Answer at page 2).

VII. GROUPING OF THE CLAIMS

Appellants agree with the Examiner's assertion that "Appellant's (*sic*) brief includes a statement that the claims stand or fall together" (Examiner's Answer at page 2).

VIII. CLAIMS APPEALED

Appellants agree with the Examiner's assertion that "(t)he copy of the appealed claims contained in the Appendix to the brief is incorrect with regards to the presentation of Claim 2" (Examiner's Answer at page 2), due to the substitution of the word "encoding" for the term "that encodes", and agree that the claims presented on page 3 of the Examiner's Answer are the correct pending claims.

IX. PRIOR ART OF RECORD

Appellants **completely and totally** disagree with the Examiner's account of the Prior Art of Record, listed on page 4 of the Examiner's Answer. Appellants note for the record that **NONE** of the art cited by the Examiner in the First Office Action on the merits in this case, which was mailed on August 12, 2002 ("the First Action") is included in the Examiner's account of the Prior Art of Record, and that **NO** art was cited by the Examiner in the Final Office Action in this case, which was mailed on February 5, 2003 ("the Final Action"). Appellants point out that the **only** art cited by the Examiner with regard to the rejections of record are Hirohata *et al.* (EMBL Accession Number AF176313), Fahrenholz *et al.*, *Ann. N. Y. Acad. Sci.* **920**:215-222, 2000, Massova *et al.*, *FASEB J.* **12**:1075-1095, 1998, Published PCT Patent Application Number WO200121658-A1, Published PCT Patent Application Number WO200154474-A2, and Published PCT Patent Application Number WO200039284-A1. Appellants further point out that the first seven references listed in the Examiner's account of the Prior Art of Record (Venter et al., Science 291:1304-1351, 2001; GenBank Accession Number NM_139238; GenBank Accession Number NM_052866; U.S. Patent Number 5,817,479; U.S. Patent Number 5,654,173; U.S. Patent Number 5,552,281; and U.S. Patent Number 6,340,583) are references that were cited **by Appellants** in either the response filed on November 12, 2002 to the First Action ("Response to the First Action"), the response filed on July 7, 2003 to the Final Action ("Response to the Final Action"), or both, **not the Examiner**, and that the Examiner did not even specifically cite **ANY** of these references in either the First Action or the Final Action. Appellants additionally point out that the last reference listed in the Examiner's account of the Prior Art of Record (NCBI Single Nucleotide Polymorphism, www.ncbi.nlm.hig.gov/SNP/, March 1, 2001) is cited **for the first time** by the Examiner in the **Examiner's Answer**.

X. ARGUMENT

A. Do Claims 1-4 Lack a Patentable Utility?

Appellants do not wish to restate all of the arguments presented in the Appeal Brief concerning the Examiner's allegation that claims 1, 2 and 5-10 lack a patentable utility, and instead incorporate the entirety

of Section VIII(A) of the Appeal Brief at this point herein by reference. However, Appellants are compelled to specifically address certain arguments presented in the Examiner's Answer for the record.

Appellants pointed out both in the Appeal Brief that the present nucleic acid sequences have utility in forensic analysis, as described in the specification as originally filed (see, for example, the specification as originally filed, at least at page 3, line 15, and from page 11, line 31 to page 12, line 27). The Examiner continues to question this asserted utility, because "virtually any gene on a human chromosome will exhibit one or more polymorphisms, which could be used in forensics" (the Examiner's Answer at page 11, emphasis in original). As pointed out by Appellants in the Appeal Brief, this argument is flawed in a **number** of respects. First, until a polymorphic marker is actually described it cannot be used in forensic analysis. Put another way, simply because there is a likelihood, even a significant likelihood, that a particular nucleic acid sequence will contain a polymorphism and thus be useful in forensic analysis, until such a polymorphism is actually identified and described, such a likelihood is **meaningless**. The Examiner once again appears to be attempting to use the information presented for the first time by Appellants in the instant specification as hindsight verification that the presently claimed sequence would be expected to have polymorphic markers. Such hindsight analysis based on Appellants discovery is completely improper. Second, the Examiner is **clearly** confusing the requirements of a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, which is clearly an improper standard. The fact that other polymorphic markers have been identified in other genetic loci, or that the use of the presently described polymorphic markers will provide additional information concerning the prevalence of these markers in certain subpopulations, does not mean that use of the polymorphic markers identified by Appellants' in forensic analysis is not a specific utility. As clearly stated by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991; "*Carl Zeiss*"):

> An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Following directly from the quote above, an invention does **not** need to be the best or **only** way to

accomplish a certain result. Thus, the question of whether or not **other** nucleic acid sequences contain polymorphic markers is **completely irrelevant** to the present utility inquiry. The **only** relevant question in regard to meeting the standards of 35 U.S.C. § 101 is whether **every** nucleic acid can be so used - and the clear answer to this question is an emphatic **no**. Just because other, or even more useful, polymorphic sequences from the human genome have been described does not mean that the use of the presently described polymorphic markers for forensic analysis is not a specific utility. Importantly, the holding in *Carl Zeiss* is **mandatory legal authority** that essentially controls the outcome of the present case. This case, and particularly the cited quote, **directly** rebuts the Examiner's argument. Furthermore, the requirement for a unique utility is clearly not the standard adopted by the Patent and Trademark Office. If every invention were required to have a unique utility, the Patent and Trademark Office would no longer be issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human diseases, such as cancer, just to name a few particular examples, because the utility of each of these compositions is applicable to the broad class in which each of these compositions falls: all batteries have the same utility, specifically to provide electrical power; all automobile tires have the same utility, specifically for use on automobiles; all golf balls and golf clubs have the same utility, specifically for use in the game of golf; and all cancer treatments have the same utility, specifically, to treat cancer. However, only the briefest perusal of virtually any issue of the Official Gazette provides numerous examples of patents being granted on each of the above compositions nearly every week. Furthermore, if a composition needed to be unique to be patented, the entire class and subclass system would be an effort in futility, as the class and subclass system serves solely to group such common inventions, which would not be required if each invention needed to have a unique utility. In view of the above standards and "common sense" analysis, there can be little question that the present sequence clearly meets the requirements of 35 U.S.C. § 101.

The Examiner then states that this is not a specific utility because "Appellants have not identified any particular reason for use of a particular polymorphism in forensic analysis of the target gene or any particular benefit that would derive from analysis of a polymorphism in the target gene", and that "(i)f further research were to show that the instant polymorphism is associated with a specific disease, then using the polynucleotide of SEQ ID NO:1 to genetically screen for said disease would be a specific utility (the

Examiner's Answer bridging pages 11 and 12). Appellants reiterate that the use of the presently identified polymorphisms in **forensic** analysis does **not** require an "association with a specific disease". The Examiner's argument is thus **completely without merit**, and in **no way** supports the allegation that the present invention lacks a patentable utility.

Furthermore, Appellants note that the Examiner cites the need for "further research" (the Examiner's Answer at pages 12, 15, 20) or "further experimentation" (the Examiner's Answer at page 20) throughout the Examiner's Answer to support the allegation that the present invention lacks a patentable utility. Appellants reiterate that the standard for meeting the requirements of 35 U.S.C. § 101 is not whether "further research" or "further experimentation" is required to practice certain aspects of the claimed invention, but whether **undue** experimentation would be required to practice the claimed invention. The widespread use of polymorphisms such as those described by Appellants in forensic analysis every day **strongly** argues against such a use requiring "undue experimentation". In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (CCPA 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988). Thus, the Examiner's argument does not support the alleged lack of utility, and the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Examiner next states that "such a utility is presently only potential, and not currently available in practical form" (the Examiner's Answer at page 12). Appellants hardly know where to begin. Naturally occurring genetic polymorphisms such as those described in the specification as originally filed are both the basis of, and critical to, *inter alia*, forensic genetic analysis intended to resolve issues of, for example, identity or paternity. Forensic analysis based on polymorphisms such as those identified by Appellants is used to positively identify or rule out suspects in many criminal cases, and in identifying human remains.

Paternity determination is based on polymorphisms such as those identified by Appellants to positively identify or rule out individuals suspected of fathering a particular child. Therefore, Appellants find the Examiner's position particularly difficult to comprehend. What could be possibly be more substantial and real world than the loss of an individual's freedom or life through incarceration? What could be possibly be more substantial and real world than the positive identification of human remains? What could be possibly be more substantial and real world than the impact, both economic and emotional, that the results of a paternity analysis has on the individuals directly and indirectly involved? These are all well known and generally accepted uses of polymorphisms such as the polymorphisms identified by Appellants. Without such identified polymorphisms, the skilled artisan would not be able to carry out such forensic or paternal analyses. Thus, the Examiner's argument once again in **no way** supports the allegation that the presently claimed sequence lacks a patentable utility.

The Examiner next states that "(b)atteries, automobile tires, golf balls, golf clubs, and methods of treatment for a variety of human diseases each have a specific utility that is known to the public", and that "(a)ll new patents issued for said products and methods are an improvement and/or variation on the well-established specific utility" (the Examiner's Answer at page 12). Appellants respectfully point out that there is **absolutely no requirement** in United States patent law for an invention to be an improvement over the art in order to be patentable; instead this smacks of the requirement of certain **foreign** patent offices for a "technical advantage". Further, the polymorphisms described by Appellants are in fact a "variation on the well-established specific utility" of polymorphisms in forensic analysis. Thus, rather than supporting the Examiner's position, this argument actually supports the Appellants' position that the present invention in fact has a patentable utility. As pointed out by Appellants in the Appeal Brief, as the presently described polymorphisms are a part of the family of polymorphisms that have a well established utility, the Federal Circuit's holding in *In re Brana,* (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*") is directly on point. Thus, the Examiner's argument once again in **no way** supports the allegation that the presently claimed sequence lacks a patentable utility.

Furthermore, Appellants detailed additional examples of the utility of the present nucleotide sequences, such as in assessing gene expression patterns using high-throughput DNA chips, and in

determining the genomic structure of the protein encoding regions of the corresponding human chromosome. The Examiner continues to question these assertions of utility, because "any human polynucleotide" can be used in these applications (the Examiner's Answer at page 18). Appellants pointed out in the Appeal Brief that these arguments are flawed in a number of respects. However, Appellants wish to emphasize that the Examiner is once again clearly confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, which is clearly an improper standard (*Carl Zeiss, supra*). The holding in *Carl Zeiss* clearly establishes that the fact that **other** polynucleotides can be used in assessing gene expression patterns and determining the genomic structure of the protein coding regions of the corresponding human chromosome is **completely irrelevant** in assessing the requirements under 35 U.S.C. § 101. The **only** relevant enquiry with regard to patentability under 35 U.S.C. § 101 is whether **every** polynucleotide can be used in assessing gene expression patterns and determining the genomic structure of the protein coding regions of the corresponding human chromosome, and the answer is an emphatic **no**. Once again, the holding in *Carl Zeiss* is **mandatory legal authority** that is directly applicable to the present appeal, and **directly** rebuts the Examiner's argument. Thus, the Examiner's argument does not support the alleged lack of utility.

Additionally, Appellants pointed out in the Appeal Brief that, regarding the utility requirements under 35 U.S.C. § 101, the Federal Circuit has clearly stated "(t)he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 185 F.3d 1364, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal Circuit has stated that "(t)o violate § 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); "*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Cross* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed that "anything under the sun that is made by man" is patentable (*State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs.*

Chakrabarty, 447 U.S. 303, 206 USPQ 193 (U.S., 1980)).

The Examiner seems to discount the case law cited by Appellants, stating "(i)n *Juicy Whip Inc. v. Orange Bang Inc.*, the issue of utility was discussed in regard to a juice dispenser, in *Brooktree Corp. v. Advanced Micro Devices, Inc.*, the issue of utility was discussed in regard to digital analog conversion circuitry, and in *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, the issue of utility was discussed in regard to a business method" (the Examiner's Answer at page 24). Appellants respectfully point out that the holding in these cases is **mandatory legal authority**, and that the Examiner **must** follow the precedent as applied to the broad issue at hand in each cited case, unless a case is specifically limited to it's facts by the **Court itself**. Furthermore, Section 101 of the Patent Act of 1952, 35 U.S.C. § 101, provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may obtain a patent on the invention or discovery. Appellants point out that 35 U.S.C. § 101 covers devices (machines) as well as compositions, and makes no distinction between the two with regard to meeting the burden of complying with 35 U.S.C. § 101. Additionally, *Juicy Whip Inc. v. Orange Bang Inc.* cites *Brenner v. Manson*, 383 U.S. 519 (1966), which the Examiner **obviously** believes is relevant to the present case, since the Examiner **herself** cites this exact case **three times** in the Examiner's Answer (the Examiner's Answer at pages 8, 13, and 15). Also, *Diamond vs. Chakrabarty, supra*, specifically concern compositions. Thus, this argument is completely improper, and totally fails to support the alleged lack of utility of the presently claimed compositions.

For each of the foregoing reasons, as well as the reasons set forth in the Appeal Brief, Appellants submit that the rejection of claims 1-4 under 35 U.S.C. § 101 must be overruled.

B. Are Claims 1-4 Unusable Due to a Lack of Patentable Utility?

Regarding the rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by either a clear asserted utility or a well-established utility, Appellants submit that as claims 1-4 have been shown to have "a specific, substantial, and credible utility", as detailed in Section X(A) above, as well as

Section VIII(A) of the Appeal Brief, the present rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, cannot stand.

Appellants therefore submit that the rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, must be overruled.

XI. CONCLUSION

Appellants respectfully submit that, in light of the foregoing arguments, the Final Action's conclusion that claims 1-4 lack a patentable utility and are unusable by the skilled artisan due to a lack of patentable utility is unwarranted. It is therefore requested that the Board overturn the Final Action's rejections.

Respectfully submitted,

March 22, 2004
Date

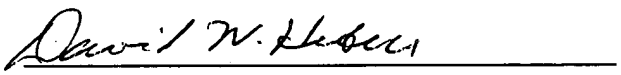

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TABLE OF AUTHORITIES

CASES

STATUTES